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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,517	12/04/2003	Kazuko Handa	116653-008	7179
29180	7590	06/16/2006	EXAMINER	
BELL, BOYD, & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			ISSAC, ROY P	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,517

Applicant(s)

HANDA ET AL.

Examiner

Roy P. Issac

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/9/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Status of the Application

The current application is a continuation of U.S. Application # 10/076,292, now abandoned, which is a continuation of 09/397,961, now abandoned, which claims priority from PCT/US96/06120, filed 03 May, 1996, and is a continuation in part of U. S. Application # 08/353328, filed 05 December, 1994, now abandoned.

The examiner notes that the Applicant has presented neither arguments nor substantive amendments preliminarily in the instant continuing case. There were no unconsidered arguments or amendments in the parent case.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 6 is objected to as informal because line 1, "whrein" should be "wherein."

Claims 2-4, 7 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the

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claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 2 and 3 replace NeuAc of claim 1 with anionic groups. This replacement does not further limit claim 1.

Claim 4 replaces fucose with substituted fucose groups that are not specified in claim 1. Thus claims 4 do not further limit claim 1.

Claim 7 and 17, which depends from claim 1 and 8, respectively, replaces NeuAc with deaminated neuraminic acid. Deaminated neuraminic acid is not included in claim 1. Thus, claim 7 is not further limiting claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Each of claims 1 and 6, from which all other claims depend, is indefinite in the recitation of "an isolated oligosaccharide," followed by a structural formula that is incomplete, and therefore cannot be isolated in the form shown. Specifically, the structural formula does not provide for any terminal group attached at the 1-position of GlcNAc.

Claim 4 is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 replaces fucose one of the listed substituted fucose moieties. However, it is not clear whether one of the fucose moiety is replaced or whether every fucose moiety is replaced.

Claim 5 is further rejected under 35 U.S.C 112, second paragraph, as being indefinite, because claim 5 refers to "repeating N-acetylactosamine subunits containing R₁." However the R₁ in the oligosaccharide in Claim 1 is not repeating.

Claim 11 is indefinite because claim 10, from which it depends, does not positively recite that the carrier contains serine or threonine.

Claim 15 is unclear as to how an oligosaccharide compound may comprise a liposome membrane.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brandley et. al. (U.S. Patent # 5211936, PTO-1449, Included by the Applicant), in view of Rao et. al (PTO-892, Cited by the examiner).

Brandley et. al. discloses compounds of the type claimed by the Applicant. (Column 5, line 64, to Column 6, line 25). The compounds have from 0-10 N-acetyllactosamine moieties. (Column 6, lines 17-23). They can be fucosylated in the D or E positions. (Column 6, lines 18-15). Furthermore, Brandley discloses inclusion of such compounds in compositions for pharmaceutical use. (Column 3, lines 1-7). The compounds may be attached to a carrier via a linker. (Column 6, lines 20-25), or may be formulated with liposome vesicles. (Column 21, lines 15-19). The glycolipids with ELAM-1 ligands were derived from leukocytes collected from patients. (Column 8, lines 1-5). Brandley et. al. further discloses methods for isolation and characterization of ligands. (Column 16, lines 60-Column 18). Brandley et. al. also discloses ligands where the fucos moiety is removed. (Column 12, lines 28-36).

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Brandley does not expressly disclose that specific compounds of the length encompassed by Applicant's claim may be isolated. In addition, replacement of sialic acid with other anionic moieties is not taught.

Rao et. al. teaches that only the charge group of the sialic acid is essential and that the sialic acid group can be replaced by carboxylate and sulfate groups. (Page 19663, Column 2, lines 7-11). Note that both sulfate and carboxylate are anionic groups.

It would have been obvious for a person of ordinary skill in the art at the time the invention was made to provide isolated oligosaccharide compounds having varying numbers of repeated N-acetyllactosamine moieties, and to formulate them as pharmaceutical compositions.

One having ordinary skill in the art would have been motivated to do so because Brandley had taught compounds generically represented by the structure in reference claim 1 and claim 8 which embraces the structure of Applicant's claims 1 and 8. Selection of any compound embraced by the generic structure of Brandley would therefore be prima facie obvious. Replacement of the anionic group NeuAc with another anionic group would also have been obvious because such a substitution would advantageously maintain the overall anionic character of the compound. Furthermore, Brandley had recognized that a 2→3 linked terminal NeuAc residue was not essential (Brandley, Claim 1), so the ordinarily skilled worker would have reasonably expected such substituted compounds to be pharmaceutically useful. Substitution of fucose analogues for

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fructose is considered to be prima facie obvious in view of marked structural similarity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac
Patent Examiner
Art Unit 1623
April 28, 2006


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